

9:10


JUN 28 2000

FDA Hearing on OTC Drugs
June 28, 2000

Thomas J. Donegan
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance
Association

COON-1256

TS 2



FDA Hearing on OTC Drugs

June 28, 2000

James Leyden, M.D.


University of Pennsylvania School of Medicine
Philadelphia, Pennsylvania



CTFA

- 106 Year Old Trade Association
- Represent 600 Companies
 - 300 Manufacture or Distribute Personal Care Products (Cosmetics and Drugs)
 - 300 Supply Goods and Services


Many CTFA Members Manufacture or Distribute Products that Are Regulated as Both Cosmetics and Drugs



Rx – OTC – Cosmetic-Drugs

Broad Spectrum of Products

- Heart Drugs to Antiperspirants
- Rx to OTC Switches Allow Flexibility
 - Consumer Availability and Choice Where Safety Permits
- Greater Flexibility Should Be Allowed for OTC Monograph Drugs



What are Cosmetic-Drugs?

- Sunscreens
- Antiperspirants
- Antidandruff Shampoos
- Antimicrobial Soaps and Washes
- Skin Protectants
- Acne Remedies
- Oral Care Products



Why Are They Different?

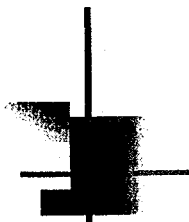
- Different Marketing Channels
 - In many cases they are purchased for their cosmetic attribute, but also provide important drug benefits
 - Broad consumer availability provides a public health benefit
- Small packages (convenience sizes) are essential for consumers to realize the benefit from these products.



The OTC Drug Review

■ Issues

- OTC Drugs = Wide Variety of Products
- 1972 to 2000 and beyond
- FDA Must Understand the Marketplace for the Products it Regulates
- International Harmonization
- Flexibility



OTC Monograph Flexibility


What is the Problem?

- Process is too slow
- Failure to Distinguish Between NDAs and Monograph Process
 - Monograph Process Should be More Open
 - Need for More Flexibility and Consumer Choice
- Need to Recognize New Ingredients
- Need to Recognize New Product Forms



OTC Monograph Flexibility

- What is the Problem?
 - Failure to Rapidly Update Agency Knowledge
 - Science
 - Formulation Technology
 - Testing Methods



OTC Monograph Flexibility

- What is the Problem?

- International Harmonization

- Material Time and Extent Barriers
- Labeling Harmonization Where Possible
- Cosmetics in Europe – Drugs in the U.S.



OTC Monograph Flexibility


- What is Necessary?
 - Increased resources and focus on monograph issues (No change in the law is necessary)
 - FDA policy encouraging more frequent communication with interested parties throughout the rulemaking process
 - Faster review and approval of new active ingredients (domestic and foreign)



OTC Monograph Flexibility


- What is Necessary?

- More FDA outreach to understand how the marketplace and products are evolving
- Cooperation with Foreign Governments and the International Industry (CHIC Process for CFSAN and CDER is positive step)
- Flexibility for Cosmetic-Drugs
 - Broad Availability of Cosmetic-Drugs for Consumers in Convenient, Attractive to Use Formulas
 - If it isn't used, it can't be effective



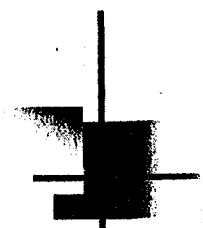
Two Case Studies

- 1. OTC Drug Labeling Regulation
- 2. Sunscreen Monograph




Case Study – OTC Labeling

- Rulemaking applied to all OTC Drugs
- Rigid format requirements for labeling
- Sound concept – flawed execution
- Barrier to International Harmonization
- Failure to recognize the broad range of products that constitute OTC drugs
 - Cough and cold to antiperspirants
 - Small packages for consumer convenience
 - Consumer needs sacrificed for “one size fits all” philosophy




Case Study - Sunscreens

- Sunscreens Provide Important Public Health Benefits
- Sunscreens prevent disease
 - Skin Cancer
- Disease Prevention Should Have High Priority
- Manufacturers Should Be Permitted to Communicate About Product Benefits with Doctors and Patients through Labeling




Case Study - Sunscreens

- The World at the Start of the OTC Review
 - Traditional Sunscreens for Beach Use
 - No System for Measuring Protection
 - Less Knowledge Linking Sun Exposure to Skin Cancer
 - Role of UVA Not Fully Understood
 - Fewer Active Ingredients




Case Study - Sunscreens

- The World in 2000
 - Beach/Outdoor Products
 - Sport Products
 - Skin Care and Foundation Products
 - Lipsticks
 - Improved formulation technology for all products to make them more attractive for consumer use



Case Study - Sunscreens


- The World in 2000
 - Better Understanding of Health Benefits
 - Sunburn Protection
 - Skin Cancer
 - Anti-aging
 - Better Protection – Better Measurements
 - High SPF Products
 - UVA Protection



Case Study - Sunscreens

FDA Should Encourage Sunscreen Products
that Further Public Health and Prevent
Disease

- Encourage Innovation
- Encourage Broad Availability as Traditional Drugs
and Cosmetic-Drugs
 - The cosmetic industry has provided major benefit to the
consumer by making sunscreen protection available in a
wide range of cosmetic products



Case Study - Sunscreens

- FDA Should Not Be A Barrier to Innovation and Communication
 - Truthful Labeling Should Be Allowed
 - High-SPF Products
 - Anti-aging benefits
 - Manufacturers Should Be Given Some Flexibility in How They Communicate with the Consumer.
- Consumers are better informed and want information.



Conclusion

- Self-Medication is a Critical Part of our Healthcare System
- FDA Should Be At the Leading Edge of Knowledge about OTC Drug Products
- FDA Needs Adequate Resources and Focus for OTC Drugs
- FDA Should Work Quickly to Resolve Safety and Efficacy Issues
- FDA Should Let the OTC Drug Marketplace Work Efficiently with Minimal Interference